



IMDRF

International Medical
Device Regulators Forum

**Regulated Products Working Group -
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Open Stakeholder Meeting
September 2015**

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Update

- Consulted on a Draft Assembly and Technical Guide to support the IMDRF pilot
- Consulted on an IMDRF ToC folder structure (templates)
- Updated the IMDRF ToC Pilot Plan
- An Expression of Interest Letter was posted



Pilot Plan

- Australia, Brazil, Canada, China, EU and United States will be participating in the IMDRF ToC
- Regional pilots are also currently being undertaken by some IMDRF members.



Proposed Timelines

Initiation of pilot

Sep 2015

Close of pilot (minimum of 12
months duration)

Sep 2016



Assembly and Technical Guide

- This document is intended to supplement the IMDRF ToC Pilot Plan and describe additional harmonized guidelines for the acceptable folder structure and file format(s) for ToC-based submissions.
- Public comment period closed June 1, 2015
- 44 comments were received to the Assembly and technical guide and folder structure consultation
- File folder naming convention and Folder structure being the most common concerns



IMDRF TOC Update

- Request for Expressions of Interest and updated Pilot Plan was posted on 21st of July 2015
- There are now 26 expressions of interest, currently 4 potential multi-jurisdictional.



Progress

- Assembly and technical guide updated based on comments received
- Update to the TOC structure to address concerns raised
- Feedback template for industry and regulators developed
- Estimated completion early September 2015



Next Steps

- Feedback to Stakeholders on Consultation comments
- Provide updated Assembly and Technical guide and folder structure to Stakeholders who have expressed interest in participation in the pilot by mid Sept 2015
- Convene a stakeholder teleconference by end of September 2015.



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Thank you